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(54) **Rapid exchange stent delivery balloon catheter**

Schnellaustausch-Stentanbringungsballonkatheter

Catheter à ballon à échange rapide pour pose de stent

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**EP 0 784 966 B1**

## Description

### TECHNICAL FIELD OF THE INVENTION

[0001] The present invention generally relates to balloon catheters and, more particularly, to a rapid exchange stent delivery balloon catheter.

### BACKGROUND OF THE INVENTION

[0002] The use of balloon catheters to treat strictures, stenoses, or narrowings within various parts of the human body is well known. In a typical procedure, for example to dilate a stenosis in the coronary arteries, a relatively large guiding catheter is inserted into the patient's arterial system in the groin. The guiding catheter is then advanced through the arteries to a location near the patient's heart. A small wire guide is then inserted into the guiding catheter and advanced to the distal end of the guiding catheter, at which point it is steered to extend through the stenosis in the coronary arteries. A balloon catheter is then advanced over the wire guide until the deflated balloon lies across the stenosis. A working fluid is then pumped through the balloon catheter, thereby inflating the balloon and dilating the passage through the stenosis.

[0003] After such a dilatation procedure, it is often found desirable to install a stent in the area of the stenosis in order to ensure patency of the lumen in the artery. Such a stent is delivered on the end of an inflatable balloon stent delivery catheter. The deformable stent is wrapped around the deflated balloon of the catheter and the catheter is inserted into the patient's body to the location of the stenosis. When the balloon of the stent delivery catheter is inflated, the stent is plastically deformed to an expanded condition, the balloon is deflated, and the stent delivery catheter is withdrawn, leaving the expanded stent in place to preserve the patency of the arterial lumen. An inflatable balloon stent delivery catheter comprising a catheter shaft defining an inflation lumen, an inflatable balloon sealed at its distal end, a tube-like end-section with a guide lumen for a guide wire at the distal end of the balloon and a catheter tip, wherein the distal end of the inflation lumen opens into and is in fluid communication with an interior of the inflatable balloon is known from EP-A-0 732 084 which is a document falling under Art. 54(3) EPC. Because such stent delivery catheters have wire guide lumens which extend the entire length of the catheter, they cannot be inserted to the stenosis site over the wire guide which is used to insert the balloon angioplasty catheter (such wire guides are too short). Therefore, after the stenosis has been dilated, the balloon angioplasty catheter and wire guide are removed from the guiding catheter and a second wire guide, or exchange wire guide, is inserted through the guiding catheter and steered to the stenosis location. The exchange wire guide is more than twice as long as the stent delivery catheter because it is necessary

that the wire guide protrude from the patient's body by a length greater than the length of the stent delivery catheter. This allows the exchange wire guide to be held steady with the physician's hand while the stent delivery catheter is advanced over the exchange wire guide. Once the distal end of the stent delivery catheter has been placed within the area of the dilated stenosis, the balloon of the stent delivery catheter may be inflated, thereby plastically deforming the stent in the region of the dilated stenosis. The balloon of the stent delivery catheter is then deflated, allowing the stent delivery catheter to be withdrawn, leaving the expanded stent in place. The exchange wire guide and the guiding catheter are then withdrawn, thereby completing the operation.

[0004] In situations where physicians find it desirable to install a stent after the balloon angioplasty procedure, the need to replace the wire guide with an exchange wire guide is a cumbersome and undesirable requirement. This is due to the fact that it is necessary that the second exchange wire guide be steered through the patient's arterial system until it reaches the location of the original stenosis. Furthermore, the great length of the exchange wire guide which extends outside of the patient's body must sometimes extend beyond the sterile area of the surgical table.

[0005] There is therefore a need in the prior art for a stent delivery catheter which may be used with the same wire guide that is used to steer the balloon angioplasty catheter. The present invention is directed toward meeting this need.

### SUMMARY OF THE INVENTION

[0006] The present invention relates to a rapid exchange stent delivery balloon catheter which allows exchange from a balloon angioplasty catheter to a stent delivery catheter without the need to replace the angioplasty catheter wire guide with an exchange-length wire guide before exchanging the catheters. The stent delivery catheter of the present invention includes a relatively short wire guide shaft which is bonded to the catheter shaft only at a location distal to the inflation lumen.

[0007] In one form of the invention, a rapid exchange stent delivery balloon catheter is disclosed, comprising a catheter shaft defining an inflation lumen, the inflation lumen having a proximal end and a distal end; an inflatable balloon having a proximal end and a distal end; a wire guide shaft defining a wire guide lumen, the wire guide shaft having a proximal end and a distal end; and a catheter tip having a proximal end and a distal end; wherein the distal end of the inflation lumen opens into and is in fluid communication with an interior of the inflatable balloon, the distal end of the inflatable balloon is sealed by the proximal end of the catheter tip, and the wire guide shaft is coupled to the catheter tip, said coupling being completely distal of the distal end of the in-

flatable balloon.

[0008] In another form of the invention, a balloon catheter stent configuration is disclosed comprising a catheter shaft defining an inflation lumen having a proximal end and a distal end; an inflatable balloon having a proximal end and a distal end; a wire guide shaft defining a wire guide lumen, said wire guide shaft having a proximal end and a distal end; a catheter tip having a proximal end and a distal end; and a stent mounted on and surrounding said inflatable balloon and wire guide shaft; wherein the distal end of the inflation lumen opens into and is in fluid communication with the inflatable balloon, the distal end of the inflatable balloon is sealed by the proximal end of the catheter tip, and the wire guide shaft is coupled to the catheter tip, said coupling being completely distal of the distal end of the inflatable balloon.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. 1 is a partial cross-sectional side view of a first embodiment rapid exchange stent delivery balloon catheter of the present invention.

[0010] FIG. 2 is a first cross-sectional view of the catheter of FIG. 1 taken along the section line 2-2.

[0011] FIG. 3 is a second cross-sectional view of the catheter of FIG. 1 taken along the section line 3-3.

[0012] FIG. 4 is a third cross-sectional view of the catheter of FIG. 1 taken along the section line 4-4.

[0013] FIG. 5 is a fourth cross-sectional view of the catheter of FIG. 1 taken along the section line 5-5.

[0014] FIGS. 6A-C are cross-sectional views of a folding procedure for the catheter of FIG. 1.

[0015] FIG. 6D is a cross-sectional view of the folded catheter of FIG. 1 with a stent installed thereupon.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

[0017] Referring now to FIG. 1, a preferred embodiment of the present invention is illustrated in a partial cross-sectional side view with the balloon inflated, and indicated generally at 10. The catheter 10 includes a catheter shaft 12 defining an inflation lumen 13 which extends far enough in the proximal direction (not shown) in order to allow the proximal end of the catheter 10 to be outside of the patient's body when the inflatable balloon is placed across the stenosis. Near the distal end

of the catheter 10, the inflation lumen 13 opens into the interior of an inflatable balloon 14. The distal end of the inflatable balloon 14 is closed and merges into catheter tip 16. A stiffening wire 18 extends through the inflation lumen 13 and the interior of the inflatable balloon 14 and terminates within the catheter tip 16. The stiffening wire 18 preferably includes a small ball or other enlargement 20 at its distal end in order to anchor the stiffening wire 18 within the catheter tip 16. The stiffening wire is preferably formed from stainless steel or any other suitable stiff material. Alternatively, the stiffening wire may be made from nitinol in the superelastic condition, which would have the advantage of making the catheter 10 kink resistant. A radiopaque marker band 22 is placed around the stiffening wire 18 near the proximal end of the inflatable balloon 14, while a second radiopaque marker band 24 is placed around the stiffening wire 18 near the distal end of the inflatable balloon 14. For the purposes of the present disclosure, the ends of the inflatable balloon 14 are defined as the regions where the balloon 14 begins to taper away from its maximum radial dimension. The radiopaque marker bands 22 and 24 may be made of any radiopaque material, such as gold, tungsten, or silver. The location of the radiopaque marker bands 22 and 24 near the proximal and distal ends of the inflatable balloons 14 allow the position of the inflatable balloon 14 to be accurately determined by fluoroscopy in order to ensure proper positioning of the inflatable balloon 14 prior to inflation.

[0018] The stent delivery catheter 10 further includes a tubular wire guide shaft 26 including and defining a wire guide lumen 27 which is bonded to the rest of the catheter 10 only in the region of the catheter tip 16. The wire guide shaft 26 includes open distal and proximal ends in order to allow a wire guide to pass therethrough. The proximal end 28 of the wire guide shaft 26 is preferably cut at an angle to the transverse axis of the wire guide shaft 26. This reduces the chance of damage to the vessel wall as the catheter 10 is withdrawn. If the proximal end 28 of the wire guide shaft 26 were cut transverse to the axis of the wire guide shaft 26, such a blunt edge would be prone to damage the vessel wall as the catheter 10 is withdrawn. The proximal end of the catheter tube 12 preferably terminates with a standard female luer type fitting (not shown) for attachment to a syringe for inflation and deflation of the inflatable balloon 14.

[0019] The stent delivery catheter 10 is preferably formed from radiation cross-linked polyethylene. Stents of various types are able to grip a folded polyethylene balloon well, such balloons have fairly good strength, and catheters and balloons formed from polyethylene have good flexibility. It would also be possible to form the catheter 10 from other materials such as nylons and PET.

[0020] Referring now to FIG. 2, a cross-sectional view of the stent delivery catheter is illustrated, taken along section line 2-2. The stiffening wire 18 is visible within

the lumen 13 of the catheter shaft 12. FIG. 3 is a second cross-sectional view of the catheter 10, taken along section line 3-3. The stiffening wire 18 is visible within the expanded balloon 14, and the wire guide shaft 26 is exterior to the inflatable balloon 14 and not bonded thereto. FIG. 4 is a third cross-sectional view of the catheter 10, taken along section line 4-4. The stiffening wire 18, surrounded by the radiopaque marker band 24, is visible within the inflatable balloon 14. The wire guide shaft 26 is separate from the inflatable balloon 14 and not attached thereto. FIG. 5 is a fourth cross-sectional view of the catheter 10, taken along section line 5-5. At this point, the wire guide shaft 26 has been merged within the tip 16 of the catheter 10. The proximal end 28 of the wire guide shaft 26 extends to approximately the proximal end of the transition between the catheter shaft 12 and the inflatable balloon 14. The required length of the wire guide shaft 26 is dependent upon the overall length of the stent delivery catheter 10 and the number and severity of the tortuous vessel turns which must be executed by the catheter 10. Generally, the longer the wire guide shaft 26, the greater the trackability of the catheter 10.

[0021] Referring now to FIGS. 6A-C, the stent delivery catheter 10 is illustrated in cross-sectional view along the same section line used for FIG. 3. The balloon 14 is shown in its deflated and flattened condition. In FIG. 6A, one-half of the deflated balloon 14 is folded over the top of the wire guide shaft 26. In FIG. 6B, the other half of the deflated balloon 14 is folded over the top of the wire guide shaft 26, thereby sandwiching the first half of the inflated balloon 14 between the second half of the deflated balloon 14 and the wire guide shaft 26. Once the balloon has been folded around the wire guide shaft 26, it has a relatively small cross-sectional diameter. As illustrated in FIG. 6D, a deformable stent 30 may be placed around the folded catheter 10. The stent 30 will typically be placed around the catheter 10 in a radially contracted configuration such that the stent 30 securely hugs the folded balloon 14, thereby preventing the stent 30 from dislodging from the catheter 10 during insertion. Once the catheter 10/stent 30 have been positioned across the dilated stenosis, the balloon 14 may be inflated by injecting working fluid through the inflation lumen 13. Expansion of the balloon 14 causes radial expansion of the stent 30 until the inside diameter of the expanded stent 30 is equal to or greater than the outside diameter of the inflated balloon 14. Because the stent 30 is plastically deformed during radial expansion, it retains its expanded diameter when the balloon 14 is deflated by evacuation of the working fluid through the inflation lumen 13. At this point, the stent delivery catheter 10 may be withdrawn, leaving the expanded stent 30 in the area of the stenosis in order to maintain patency of the vessel. The stent delivery catheter 10 of the present invention may be used with any balloon expandable stent design.

[0022] The stent delivery catheter 10 of the present

invention can be used to place balloon expanded stents in several parts of the anatomy, and is not limited solely to placement of stents in the coronary arteries. For use in coronary arteries, the balloon 14 diameter should have a range of approximately 2.0-5.0 mm. The balloon length should be approximately 15-45 mm. The inside diameter of the wire guide shaft 26 (i.e. the diameter of the lumen 27) should be approximately .5 mm. The overall length of the catheter 10 should be approximately 110-180 cm. The stiffening wire should be approximately 0.25-0.38 mm (.010-.015 inches) in diameter. The distal end of the stiffening wire can be tapered in order to allow more flexibility at the distal end of the catheter 10. The distal section of the stiffening wire should be approximately 0.2-0.3 mm (.008-.012 inches) in diameter for a length of approximately 3-15 cm. proximal of the distal tip 20, at which point the stiffening wire 18 should taper up to a full stiffening wire diameter for a length of approximately 2-10 cm. The outside diameter of the catheter shaft 12 should be approximately 1-1.5 mm.

[0023] For peripheral vessels, bile ducts and other parts of the anatomy, the balloon 14 diameter should range from 5-15 mm., the balloon 14 length should be approximately 15-60 mm., the catheter shaft 12 should range up to 3.5 mm. outside diameter, and the inside diameter of the wire guide shaft 26 should go up to approximately 1.5 mm.

[0024] The stent delivery catheter 10 is preferably formed by starting with a length of tubing which is equal in cross-sectional dimensions to the desired dimensions of the catheter shaft 12. The distal end of this tubing is closed and a portion of the tubing is placed into a mold which has the shape and dimensions of the desired size of the inflated balloon 14. The section of the tubing within the mold is then heated and the interior of the tubing is pressurized such that the portion of the tubing within the mold expands to the interior dimensions of the mold. The tubing is then cooled such that the material within the mold retains the shape of the interior of the mold. The mold is then removed and the distal end of the tubing is cut distal to the distal end of the balloon at the desired distance.

[0025] A second section of tubing having dimensions desired for the wire guide shaft 26 is then placed next to the balloon 14 such that the distal end of the wire guide shaft 26 is adjacent the distal end of the tubing. A wire mandrel is then inserted into the wire guide lumen 27 until the distal end of the wire mandrel is adjacent the distal end of the wire guide lumen 27. The distal ends of the wire guide shaft 26 and the tubing are then inserted into a mold which has an interior shape and dimensions which match the distal end of the catheter 10 as illustrated in FIG. 1. The plastic within this mold is then heated to above the melting temperature of the plastic material in order to bond the wire guide shaft 26 to the newly formed catheter tip 16. The mandrel within the wire guide lumen 27 maintains the patency of this lu-

men. At the same time that the wire guide shaft 26 is being bonded to the catheter tip 16, the stiffening wire 18 is inserted through the lumen 13 and the balloon 14 such that the tip 20 extends into the molten plastic material. The end of the catheter shaft is then cooled to below the melting point of the plastic material, thereby solidifying the stiffening wire tip 20 within the distal tip 16 of the catheter and bonding the wire guide shaft 26 to the distal end 16. The mandrel is then removed from the wire guide lumen and construction of the catheter is complete.

[0026] The stent delivery catheter 10 of the present invention has the advantage that it allows the exchange from the balloon angioplasty catheter to the stent delivery catheter without the need to replace the wire guide with an exchange-length wire guide before exchanging the catheters. The wire guide is simply left undisturbed, the angioplasty catheter is removed and the stent delivery catheter is introduced. The short wire guide shaft 26 allows the operator to maintain control of the wire guide while introducing the stent delivery catheter 10. Having the wire guide shaft 26 extend from the distal end to the proximal end of the balloon 14 allows the wire guide and wire guide shaft 26 to be threaded through the interior of the stent 30 so that the wire guide and wire guide shaft 26 are inside the stent 30 when the stent 30 is expanded, and not trapped between the stent 30 and the vessel wall.

[0027] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the scope of the claims are desired to be protected.

#### Claims

1. A rapid exchange stent delivery balloon catheter (10), comprising:

a catheter shaft (12) defining an inflation lumen (13), the inflation lumen (13) having a proximal end and a distal end;  
 an inflatable balloon (14) having a proximal end and a distal end;  
 a wire guide shaft (26) defining a wire guide lumen (27), the wire guide shaft (26) having a proximal end and a distal end, wherein the proximal end of the wire guide shaft (26) is proximal to the proximal end of the inflatable balloon (14); and  
 a catheter tip (16) having a proximal end and a distal end;

wherein the distal end of the inflation lumen

(13) opens into and is in fluid communication with an interior of the inflatable balloon (14), the distal end of the inflatable balloon (14) is sealed by the proximal end of the catheter tip (16), and the wire guide shaft (26) is coupled to the catheter tip (16) completely distally of the distal end of the inflatable balloon (14).

2. The stent delivery balloon catheter of claim 1, wherein the distal end of the wire guide shaft is adjacent the distal end of the catheter tip.

3. The stent delivery balloon catheter of claim 1, wherein the proximal end of the wire guide shaft is formed at an angle to a transverse axis of the wire guide shaft.

4. The stent delivery balloon catheter of claim 1, further comprising:

a stiffening wire having a proximal end and a distal end;

wherein the stiffening wire extends through the interior of the inflatable balloon.

5. The stent delivery balloon catheter of claim 4, wherein the distal end of the stiffening wire is coupled to the catheter tip.

6. The stent delivery balloon catheter of claim 4, further comprising: at least one radiopaque marker band coupled to the stiffening wire.

7. The stent delivery balloon catheter of claim 6, wherein the at least one radiopaque marker band marks a location of at least one end of the inflatable balloon.

8. The stent delivery balloon catheter of claim 1, wherein the inflatable balloon is folded around the wire guide shaft.

9. The stent delivery balloon catheter of claim 8, further comprising:

an expandable stent disposed around the folded inflatable balloon.

10. The stent delivery balloon catheter of claim 1, wherein the catheter shaft, the inflatable balloon, the wire guide shaft and the catheter tip are formed from radiation cross-linked polyethylene.

11. The stent delivery balloon catheter of claim 4, wherein the stiffening wire is formed from stainless steel.

12. The stent delivery balloon catheter of claim 5, further comprising a spherical ball coupled to the distal end of the stiffening wire.

13. The stent delivery balloon catheter of claim 6, wherein the at least one radiopaque marker band is formed from gold.

14. A balloon catheter stent configuration comprising:

a catheter shaft (12) defining an inflation lumen (13) having a proximal end and a distal end; an inflatable balloon (14) having a proximal end and a distal end; a wire guide shaft (26) defining a wire guide lumen (27), said wire guide shaft (26) having a proximal end and a distal end, wherein the proximal end of the wire guide shaft (26) is proximal to the proximal end of the inflatable balloon (14); a catheter tip (16) having a proximal end and a distal end; and a stent mounted on and surrounding said inflatable balloon (14) and wire guide shaft (26);

wherein the distal end of the inflation lumen (13) opens into and is in fluid communication with the inflatable balloon (14), the distal end of the inflatable balloon (14) is sealed by the proximal end of the catheter tip (16), and the wire guide shaft (26) is coupled to the catheter tip (16) completely distally of the distal end of the inflatable balloon (14).

#### Patentansprüche

1. Stent-Schnellsetzballonkatheter (10) mit:

einem Katheterschaft (1), der ein Aufweillumen (13) mit einem proximalen und einem distalen Ende umschließt; einem aufweitbaren Ballon (14) mit einem proximalen und einem distalen Ende; einem Drahtführungsschaft (26), der ein Drahtführungslumen (27) definiert und ein proximales und ein distales Ende aufweist, wobei das proximale Ende des Drahtführungsschafts (26) proximal zum proximalen Ende des aufweitbaren Ballons (14) liegt; und mit einer Katheterspitze (16) mit einem proximalen und einem distalen Ende;

wobei das distale Ende des aufweitbaren Lumens (13) in den aufweitbaren Ballon (14) mündet und in Strömungsverbindung mit ihm steht, das distale Ende des aufweitbaren Ballons (14) vom proximalen Ende der Katheterspitze (16) verschlossen wird und der Drahtführungsschaft (26) weit distal

vom distalen Ende des aufweitbaren Ballons (14) mit der Katheterspitze (16) gekoppelt ist.

2. Stent-Schnellsetzballonkatheter nach Anspruch 1, bei dem das distale Ende des Drahtführungsschafts am distalen Ende der Katheterspitze liegt.

3. Stent-Schnellsetzballonkatheter nach Anspruch 1, bei dem das proximale Ende des Drahtführungsschafts zu einer Querachse des letzteren winklig ausgebildet ist.

4. Stent-Schnellsetzballonkatheter nach Anspruch 1, weiterhin mit:

einem Versteifungsdraht mit einem proximalen und einem distalen Ende;

wobei der Versteifungsdraht innen durch den aufweitbaren Ballon verläuft.

5. Stent-Schnellsetzballonkatheter nach Anspruch 4, bei dem das distale Ende des Versteifungsdrahts mit der Katheterspitze gekoppelt ist.

6. Stent-Schnellsetzballonkatheter nach Anspruch 4, weiterhin mit mindestens einem radiopaken Markierungsband, das mit dem Versteifungsdraht gekoppelt ist.

7. Stent-Schnellsetzballonkatheter nach Anspruch 6, bei dem das mindestens eine radiopake Markierungsband den Ort mindestens eines Endes des aufweitbaren Ballons markiert.

8. Stent-Schnellsetzballonkatheter nach Anspruch 1, bei dem der aufweitbare Ballon um den Drahtführungsschaft gefaltet ist.

9. Stent-Schnellsetzballonkatheter nach Anspruch 8, weiterhin mit einem aufweitbaren Stent, der um den aufweitbaren Ballon herum angeordnet ist.

10. Stent-Schnellsetzballonkatheter nach Anspruch 1, bei dem der Katheterschaft, der aufweitbare Ballon, der Drahtführungsschaft und die Katheterspitze aus durch Bestrahlung vernetztem Polyethylen ausgebildet sind.

11. Stent-Schnellsetzballonkatheter nach Anspruch 4, bei dem der Versteifungsdraht aus nicht rostendem Stahl ausgebildet ist.

12. Stent-Schnellsetzballonkatheter nach Anspruch 5, weiterhin mit einem kugelförmigen Ball, der mit dem distalen Ende des Versteifungsdrahts verbunden ist.

13. Stent-Schnellsetzballonkatheter nach Anspruch 6, bei dem das mindestens eine radiopake Markierungsband aus Gold ausgebildet ist.

14. Ballonkatheter-Stent-Anordnung mit:

einem Katheterschaft (12), der ein Aufweitlumen (13) mit einem proximalen und einem distalen Ende umschließt;  
 einem aufweitbaren Ballon (14) mit einem proximalen und einem distalen Ende;  
 einem Drahtführungsschaft (26), der ein Drahtführungslumen (27) umschließt und der ein proximales und ein distales Ende aufweist, wobei das proximale Ende des Drahtführungsschafts (26) proximal zum proximalen Ende des aufweitbaren Ballons (14) liegt;  
 einer Katheterspitze (16) mit einem proximalen und einem distalen Ende; und mit  
 einem Stent, der auf den aufweitbaren Ballon (14) und den Drahtführungsschaft (26) aufgesetzt ist und sie umgibt;

wobei das distale Ende des Aufweitlumens (18) in den aufweitbaren Ballon (14) mündet und in Strömungsverbindung mit ihm steht, das distale Ende des aufweitbaren Ballons (14) vom proximalen Ende der Katheterspitze (16) verschlossen wird und der Drahtführungsschaft (26) weit distal vom distalen Ende des aufweitbaren Ballons (14) mit der Katheterspitze (16) gekoppelt ist.

#### Revendications

1. Cathéter à ballon (10) à échange rapide pour pose de tuteur comprenant :

une tige de cathéter (12) définissant un chenal de gonflement (13), le chenal de gonflement (13) comportant une extrémité proximale et une extrémité distale ;  
 un ballon gonflable (14) comportant une extrémité proximale et une extrémité distale ;  
 une tige passe-fil (26) définissant un chenal passe-fil (27), la tige passe-fil (26) comportant une extrémité proximale et une extrémité distale, dans lequel l'extrémité proximale de la tige passe-fil (26) est proximale par rapport à l'extrémité proximale du ballon gonflable (14) ; et  
 une pointe de cathéter (16) ayant une extrémité proximale et une extrémité distale ;  
 dans lequel l'extrémité distale du chenal de gonflement (13) débouche à l'intérieur du ballon gonflable (14) et permet le passage d'un fluide, l'extrémité distale du ballon gonflable (14) est rendue étanche par l'extrémité proximale de la pointe de cathéter (16) et la tige pas-

se-fil (26) est couplée à la pointe de cathéter (16) de façon complètement distale par rapport à l'extrémité distale du ballon gonflable (14).

2. Cathéter à ballon pour pose de tuteur selon la revendication 1, dans lequel l'extrémité distale de la tige passe-fil est adjacente à l'extrémité distale de la pointe de cathéter.
3. Cathéter à ballon pour pose de tuteur selon la revendication 1, dans lequel l'extrémité proximale de la tige passe-fil est formée à un certain angle par rapport à un axe transversal de la tige passe-fil.
4. Cathéter à ballon pour pose de tuteur selon la revendication 1, comprenant en outre :
- un fil de renforcement comportant une extrémité proximale et une extrémité distale ;  
 dans lequel le fil de renforcement s'étend à l'intérieur du ballon gonflable.
5. Cathéter à ballon pour pose de tuteur selon la revendication 4, dans lequel l'extrémité distale du fil de renforcement est couplée à la pointe de cathéter.
6. Cathéter à ballon pour pose de tuteur selon la revendication 4, comprenant en outre : au moins une bande radio-opaque de marquage couplée au fil de renforcement.
7. Cathéter à ballon pour pose de tuteur selon la revendication 6, dans lequel ladite au moins une bande radio-opaque de marquage marque un emplacement d'au moins une extrémité du ballon gonflable.
8. Cathéter à ballon pour pose de tuteur selon la revendication 1, dans lequel le ballon gonflable est plié autour de la tige passe-fil.
9. Cathéter à ballon pour pose de tuteur selon la revendication 8, comprenant en outre :
- un tuteur extensible disposé autour du ballon gonflable plié.
10. Cathéter à ballon pour pose de tuteur selon la revendication 1, dans lequel la tige de cathéter, le ballon gonflable, la tige passe-fil et la pointe de cathéter sont constitués de polyéthylène réticulé par radiation.
11. Cathéter à ballon pour pose de tuteur selon la revendication 4, dans lequel le fil de renforcement est en acier inoxydable.
12. Cathéter à ballon pour pose de tuteur selon la re-

vendication 5, comprenant en outre une bille sphérique couplée à l'extrémité distale du fil de renforcement.

13. Cathéter à ballon pour pose de tuteur selon la revendication 6, dans lequel ladite au moins une bande radio-opaque de marquage est constituée d'or. 5

14. Configuration de tuteur de cathéter à ballon comprenant : 10

une tige de cathéter (12) définissant un chenal de gonflement (13) comportant une extrémité proximale et une extrémité distale ;  
 un ballon gonflable (14) comportant une extrémité proximale et une extrémité distale ; 15  
 une tige passe-fil (26) définissant un chenal passe-fil (27), ladite tige passe-fil (26) comportant une extrémité proximale et une extrémité distale, dans lequel l'extrémité proximale de la 20  
 tige passe-fil (26) est proximale par rapport à l'extrémité proximale du ballon gonflable (14) ;  
 une pointe de cathéter (16) ayant une extrémité proximale et une extrémité distale ; et  
 un tuteur monté sur et entourant ledit ballon gonflable (14) et ladite tige passe-fil (26) ; 25  
 dans lequel l'extrémité distale du chenal de gonflement (13) débouche dans le ballon gonflable (14) et permet le passage d'un fluide, l'extrémité distale du ballon gonflable (14) est rendue étanche par l'extrémité proximale de la 30  
 pointe de cathéter (16) et la tige passe-fil (26) est couplée à la pointe de cathéter (16) de façon complètement distale par rapport à l'extrémité distale du ballon gonflable (14). 35

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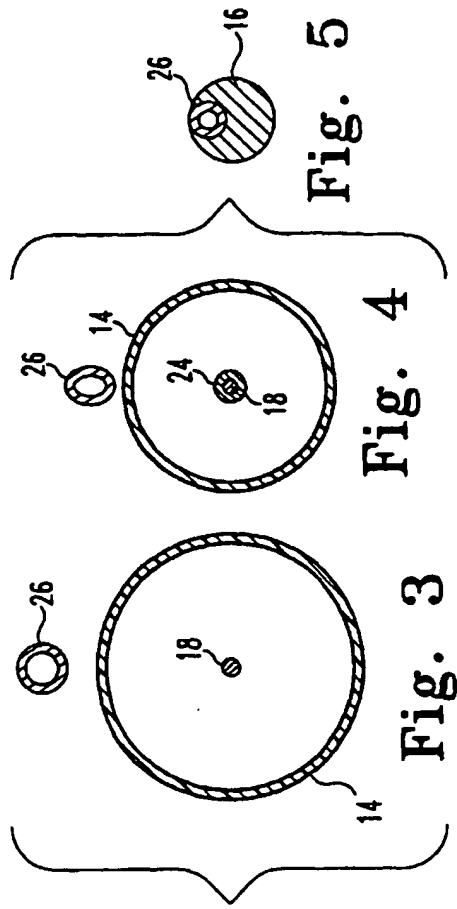
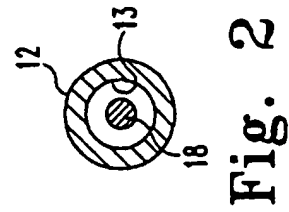
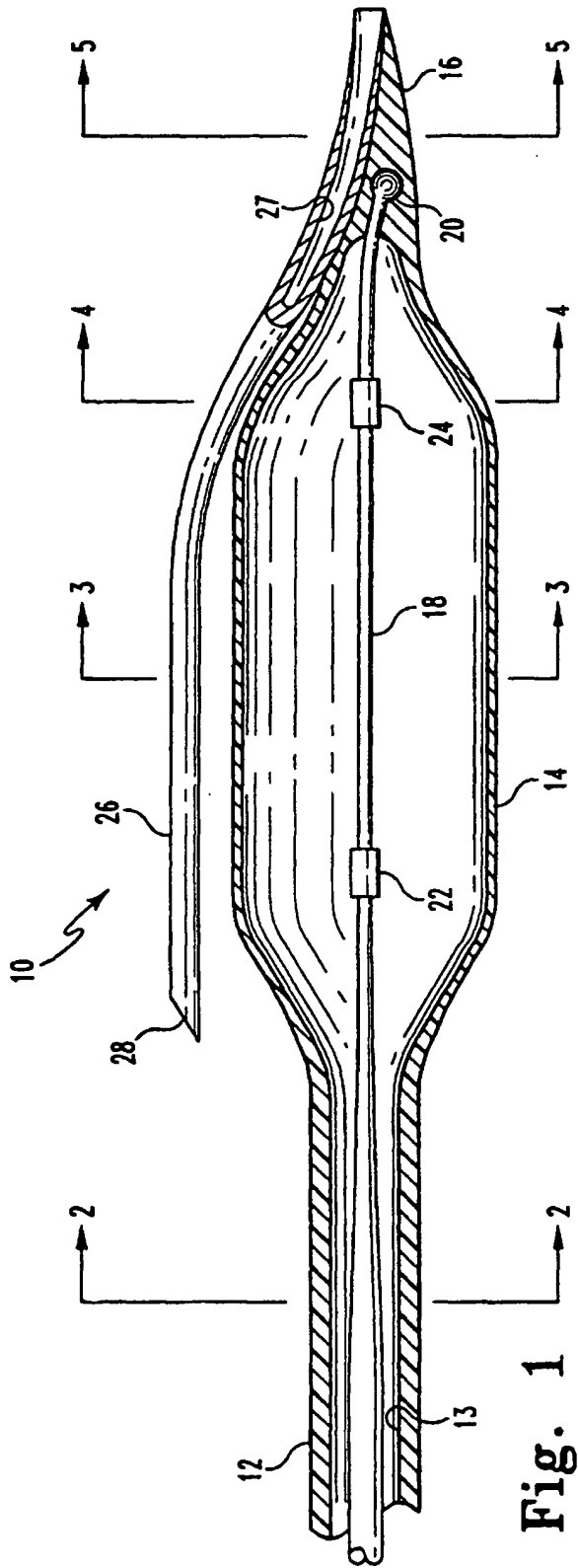


Fig. 6A

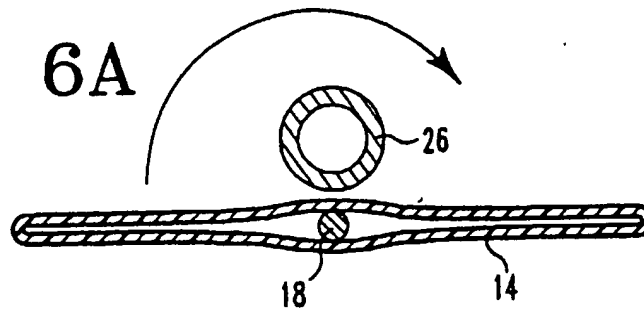


Fig. 6B

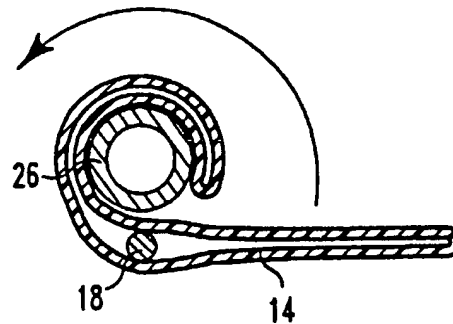


Fig. 6C

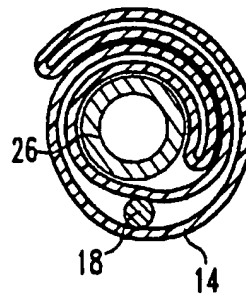


Fig. 6D

